

Remarks

Claims 1-3 and 10-13 are pending. Claims 4-9 and 14-35 have been withdrawn from consideration. Claims 2, 3, and 10-13 are amended. The claim amendments are offered to correct certain formal defects in the claims as filed and are offered free of any intent to narrow the scope of what Applicants' consider as their invention. Support for the amendments may be found throughout the specification as filed, including the documents and references cited and incorporated therein.

In view of the Examiner's previous restriction requirement, Applicant retains the right to present claims 4-9 and 14-35 in a divisional application.

The Examiner objects to Applicant's drawings pursuant to 37 CFR 1.83(a). The Office Action indicates that the hydrophilic surface within the capillary volume (claims 10-11) must be shown or the feature(s) must be cancelled from the claim. However, it is respectfully submitted that the surfaces of Applicant's claimed capillary volume are clearly indicated in the figures. Claims 10 and 11 merely provide that one of these surfaces has a particular property, namely that it is hydrophobic. The fact that the surface is hydrophobic is not a physical feature, but a property. Applicant's specification on page, 2 provides that "the surfaces of the microneedle array that are likely to come into contact with fluids during use have certain wettability characteristics. It may be preferred that these surfaces are hydrophilic, e.g., exhibit a static contact angle for water of less than 90 degrees (possibly less than about 40 degrees), so that the fluid can be spontaneously wicked via capillary pressure." Therefore, the features are shown in the figures in compliance with 37 CFR 1.83(a). Withdrawal of this rejection is respectfully requested.

35 U.S.C. §102 Rejections

Claims 1-3, of which claim 1 is independent, stand rejected under 35 USC § 102(b) as being anticipated by WO 97/03718 ("Eicher"). The Office Action asserts that the Eicher reference

discloses a microneedle device comprising a substrate, a plurality of needles, a cover and a capillary volume according to Figure 5 of the reference.

Claim 1 recites:

A microneedle device comprising:

a substrate comprising a first major surface;

at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first major surface of the substrate and a tip distal from the base;

a cover comprising a first side facing the first major surface of the substrate and a second side facing away from the substrate, wherein the at least one microneedle penetrates through the first side and the second side of the cover; and

a capillary volume located between the first major surface of the substrate and the first side of the cover; wherein the capillary volume contacts at least a portion of the base of the at least one microneedle.

However, the microneedles of the device in Eicher do not "penetrate through the first side and the second side of the cover" which serve to deliver medicaments or other substances and/or extract blood or tissue as recited in Applicant's claim 1. Therefore Eicher does not anticipate the pending claims and withdrawal of the rejection is respectfully requested.

Claims 1-3, 10-11 stand rejected under 35 U.S.C. § 102(e) as anticipated by Yeshurun, U.S. Patent No. 6,558,361 ("the '361 patent"). The Office Action asserts the reference discloses all salient structural features of the rejected claims. For the following reasons, reconsideration and withdrawal of this rejection is requested.

The Office Action indicates that Yeshurun discloses a microneedle device comprising a substrate, a plurality of microneedles over a cover 50 and a capillary volume between the substrate and the first/ under side of the cover. Yeshurun does not disclose a microneedle device set forth in Applicant's claim 1 recited above. The cover and the microneedle substrate of Applicant's invention together, define the capillary volume in fluid communication with the base of the microneedles. However, Yeshurun does not disclose "a cover comprising a first side ... and a second side..., wherein a plurality of microneedles penetrate through the first side and the second side of the cover." Yeshurun only discloses a single needle penetrating through a single cover formed around the needle. Additionally, close examination of the reference indicates that

where Yeshurun considers a plurality of needles, it also contemplates a plurality of separate covers, which is further distinguishable from Applicant's dependant Claim 2 where a plurality of needles penetrates through a single cover.

Further, the Office Action indicates that the Yeshurun reference discloses coating the microneedles with metal or metal alloy as evidenced by Arias et al. ('820). The Office Action states that the Arias reference teaches using materials to create hydrophilic-hydrophobic combinations on the microneedle substrate. Yeshurun fails to describe, teach, or suggest an hydrophilic surface within the capillary volume. Yeshurun discloses coating the microneedles with a metal or metal alloy, however, the coating is purely for mechanical strength and has nothing to do with surface hydrophilicity-hydrophobicity.

Furthermore, Arias does not cure the defects of the Yeshurun reference. The Arias reference merely discloses that combinations of materials can be used to make a hydrophilic-hydrophobic combination, but provides no teaching on what materials it considers hydrophilic or hydrophobic. The rejection of claims 1-3, and 10-11 under 35 USC § 102(e) as being anticipated by Yeshurun is improper and should be withdrawn. Withdrawal of the rejection is respectfully requested.

Claims 1-3 stand rejected under 35 U.S.C. § 102(e) as anticipated by Rosenberg, U.S. Patent Application No. 2003/0199812. The Office Action asserts the reference discloses a microneedle device comprising a substrate, a plurality of microneedles, a cover and a capillary volume between the substrate and the first/ underside of the cover.

However, although Rosenberg discloses a cover to protect the entire microneedle device (see page 4, paragraph 47 and Figure 1, "The cover 14 snaps onto the body portion to protect the microneedles and can be removed prior to use"), the microneedles in Rosenberg do not "penetrate through the first side and the second side of the cover."

Because Rosenberg fails to set forth each and every element of claim 1, Rosenberg cannot anticipate claim 1 or the claims depending therefrom. Withdrawal of the rejection is therefore respectfully requested.

35 U.S.C. §103 Rejections

Claims 12 and 13 stand rejected under 35 USC § 103(a) as being unpatentable over Yeshurun in view of U.S. Pat. No. 6,558,361 (“Chacornac”).

Applicants respectfully submit that the combination of Yeshurun and Chacornac suggested in the Office Action fails to teach or suggest all of the limitations of the rejected claims.

As acknowledged by the Office Action, Yeshurun discloses a needle with a channel within the microneedle for passage of fluids. The Office Actions acknowledges that Yeshurun fails to teach a channel on the outer surface of the microneedle. The Office Action asserts that it would have been obvious to one having ordinary skill in the art to modify the needle channels of Yeshurun with the external channel as taught by Chacornac as a mere design choice of channels which function to deliver treatment material.

Applicants respectfully submit that the proposed combination fails to overcome the deficiencies of Yeshurun because one of ordinary skill in the art would have had no motivation to combine the teachings of Yeshurun and Chacornac as suggested in the Office Action. Yeshurun discloses a needle without a channel to allow for fluid flow around the outside of the needle in Fig. 8. In Fig. 9, Yeshurun shows a needle also having a central bore and notes (column 11, lines 15-20) that such a configuration can allow for withdrawal and delivery of fluids at the same time. Because of the manner in which the needles in Yeshurun are prepared (by etching away the capillary volume between needle and cover) there is no need and thus no motivation to incorporate an outer channel on the needle in Yeshurun.

However in Applicant’s invention, an outer channel provides a clear benefit in devices made according to methods where the needles are forced through a cover film (such as in claim 36). In this instance, the outer channel may provide a means for fluid communication across the cover film in connection with the microneedles. Additionally, putting the outer channels in fluid communication with the capillary volume will typically enhance the transport of fluids through the microneedle device.

For at least the above reason, Applicant respectfully submits that the rejection of claims 12 and 13 under 35 USC § 103(a) as being unpatentable over Yeshurun in light of Chacornac

should be withdrawn. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Respectfully submitted,

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